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(71) Applicant:
**Schneider (Europe) GmbH**
**8180 Bülach (CH)**

(72) Inventor: **Théron Jacques**
**14123 Fleury sur Orne (FR)**

## (54) Seal for catheter assembly with dilation and occlusion balloon

(57) A catheter assembly for the treatment of a vessel carrying body fluid, comprising an inner first occlusion catheter (4), having a first tubular shaft (5) with a proximal end (6) and a distal end (7), a distal occlusion balloon (8) disposed at the distal end (7) of the first tubular shaft (5) and an inflation lumen (9) extending through the first tubular shaft (5) between a proximal entry (10) at the proximal end (6) and a distal exit (11) inside the distal occlusion balloon (8), and an outer treatment catheter (15,22,15'), having a second tubular shaft (16) with a central lumen (17) extending therethrough for coaxial reception of the first occlusion catheter (4), and being longitudinally displaceable with respect to the first occlusion catheter (4), further comprises a seal (21) for the proximal entry (10) of the inflation lumen (9), having an outside dimension small enough to fit within the central lumen (17) for advancing, resp. withdrawing, a treatment catheter (15,22,15') proximally onto, resp. from, the sealed first occlusion catheter (4), treatment catheters (15,22,15') are exchangeable while the distal occlusion balloon (8) is maintained in its inflated condition.

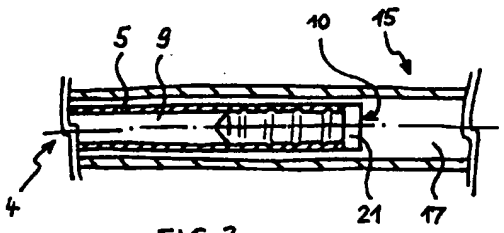


FIG. 3

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## Description

[0001] The invention relates to a catheter device for the treatment of a vessel carrying body fluid, comprising an inner first occlusion catheter, having a first tubular shaft with a proximal end and a distal end, a distal occlusion balloon disposed at the distal end of the first tubular shaft and an inflation lumen extending through the first tubular shaft between a proximal entry at the proximal end and a distal exit inside the distal occlusion balloon, and an outer treatment catheter, having a second tubular shaft with a central lumen extending therethrough for coaxial reception of the first occlusion catheter, and being longitudinally displaceable with respect to the first occlusion catheter.

[0002] A catheter device of the kind mentioned in the introduction is known for example from US 5,423,742 which is used for percutaneous transluminal angioplasty of arteriosclerotic deposits or atheroma in the carotid artery. For this treatment an outermost guide catheter is pushed through an opening in the inguinal region of the patient into the vessel, until its front opening is situated directly in front of the stenosis. An innermost occlusion catheter is then inserted into the guide catheter and placed in a way that the occlusion balloon can be stabilized in the inflated state distal of the stenosis. A central dilation catheter is then pushed over the occlusion catheter, and the dilatation balloon is positioned' in the middle of the stenosis which is now dilated in a known manner. Vessel parts which might be detached during angioplasty are prevented by the occlusion balloon from getting into the narrow and tortuous cerebral vessel system reducing thereby the risk of embolism. After treatment of the stenosis the dilatation balloon is emptied and the dilation catheter is retracted. With the occlusion catheter simultaneously inflated, vessel fluid and any detached particles present are removed by suction through the guide catheter by means of a syringe. As a result of pressure exerted by means of the syringe, vessel fluid with small particles can be washed out reaching areas of the vessel where there is no danger of embolism. Finally, the occlusion balloon is also returned to the emptied state and the catheter device is removed from the vessel.

[0003] For inflating and deflating the occlusion balloon a syringe is connected to the proximal end of the occlusion catheter. The latter must have a length greater than the length of the guide catheter plus the length of the dilation catheter, for example between 250 and 300 cm, to allow the dilation catheter being withdrawn over the occlusion catheter completely out of the guide catheter, while the occlusion balloon remains in its inflated condition. The syringe connector which might be a stop cock combines the occlusion catheter and the dilation catheter to a unit which shows disadvantages if further treatment, such as stenting or post-dilating of the widened stenosis, is necessary. The catheter unit does not allow the exchange of the dilation catheter by another catheter during the protective occlusion balloon is kept in its inflated condition, since the connector forms an obstacle which cannot be passed through the central lumen of the dilation catheter. Thus, in such a case the whole catheter unit must be replaced. On one hand this might be a rather time consuming procedure putting a lot of stress to the patient. On the other hand it raises the risk of embolism since the protective downstream occlusion of the vessel has to be interrupted.

[0004] It is therefor an object of the invention to provide a catheter device as described above which allows the exchange of a treatment catheter by another one while the occlusion catheter remains in place maintaining the occlusions ballon in its inflated condition for sealing the vessel distal of the portion to be treated.

[0005] For this a catheter device according to the invention complies with the definitions given in the characterising portion of claim 1. Where the catheter device comprises a seal for the proximal entry of the inflation lumen, having an outside dimension small enough to fit within the central lumen for advancing, resp. withdrawing, a treatment catheter proximally onto, resp. from, the sealed first occlusion catheter, it is possible to exchange treatment catheters over the positioned occlusion catheter. During replacement the seal keeps maintaining the occlusion balloon in its inflated state and does not form a stopping obstacle.

[0006] In a preferred embodiment of the invention the treatment catheter is a dilatation catheter further having a non-compliant dilatation balloon whereby subsequent treatment of a stenosis with dilatation balloons of different diameters or lengths is possible. Such ballon dilatation catheters are well known in the art, see for example EP 0 650 740 A1, and have to be adapted in their central lumen which is usually sized for the reception of a guidewire. Thus, known balloon catheter technology can be used with a slight change in a lumen diameter. In a further embodiment of the invention a balloon-expandable stent is mounted on the dilatation balloon taking advantage of the fact that dilatation catheter are commonly used instruments for the deployment of balloon-expandable stents, it is referred to US 4,733,665 as an example. Accordingly, such a treatment catheter allows scaffolding of a predilated stenosis by implanting a balloon-expandable stent immediately after having widened the stricture and while the downstream vessel system is still protected by the filled occlusion balloon.

[0007] In another preferred embodiment of the invention the treatment catheter is a stent delivery instrument loaded with a self-expanding stent. Self-expanding stents are also well known in the art and are special in that they comprise an unconstrained large diameter state which is taken by self-expansion upon removing the constraint which keeps the tubular stent in a compressed small diameter condition. For insertion into the vessel system such a stent can be loaded distally into the lumen of an outer shaft of a delivery instrument, such as it is disclosed in EP 0 775 470 A1. Having

reached the treatment site the outer shaft is withdrawn relative to an inner shaft which works as a plunger keeping the axial position of the stent while the constraint applied by the outer shaft is removed from the stent to release it. Delivery instruments for self-expanding stents are also usually inserted over a guide wire which is passed through a central lumen of the instrument. By adaption of the central guide wire lumen the deployment of self-expanding stents following balloon angioplasty is possible.

**[0008]** In a further preferred embodiment of the invention the treatment catheter is a second occlusion catheter further having a proximal occlusion balloon for sealing a vessel portion between the proximal and distal occlusion balloon. Due to the fact that the occlusion catheters are displaceable with respect to each other the length of the vessel portion to be sealed is adjustable. US 4,655,746 is incorprated herewith as a reference.The sealing can provide for a well visible access to this protion in a surgical intervention. Moreover, if according to a further preferred embodiment an annular lumen is disposed between the first and second occlusion catheter and extends between a proximal inlet and a distal outlet for infusion, resp. aspiration, of a liquid into, resp. from, the sealed vessel portion, drugs can be delivered locally to a vessel portion, i.e. without affecting the rest of the vessel system, and any reaction products or particles can be aspirated through said annular lumen.

**[0009]** In a further preferred embodiment of the invention the catheter device futher comprises an outer insertion catheter having a third tubular shaft with a through lumen for insertion, resp. retraction, of the frist occlusion catheter and of a treatment catheter into, resp. from, the vessel to be treated. This catheter serves as a guide for the occlusion and treatment catheters finding their way from the puncture which is usually placed in the inguinal region through the vessel system having a larger diameter to the portion to be treated. It is kept in place during all manipulations and can finally be used to rinse off small particles detached from the vessel wall during the treatment before the protective distal occlusion is removed.

**[0010]** Further advantages are readily apparent from an exemplary embodiment of the invention described with reference to the drawings in which

FIG. 1, 4-6 show schematic representations of a vessel section with an inserted catheter device according to the invention,

FIG. 2 shows the proximal end of the first occlusion catheter according to the invention connected to a stop cock,

FIG. 3 shows a longitudinal section through the sealed proximal end of the catheter device.

**[0011]** FIG. 1 and FIG.s 4-6 show a portion of a blood vessel 1 which, downstream from a lateral branch 2, was partially closed by a stenosis formed by arterial plaque deposit 3. The inserted catheter device comprises an inner first occlusion catheter 4 having a first tubular shaft 5 with a proximal end 6 (not shown) and a distal end 7, a distal occlusion balloon 8 and an inflation lumen 9 extending through the first tubular shaft 5 between a proximal entry 10 (not shown) and a distal exit 11 inside the distal occlusion balloon 8. The distal occlusion balloon 8 is disposed at the distal end 7 of the first tubular shaft 5 and is positioned in its inflated condition distally of the area affected by plaque deposit 3. This is to establish a protective seal for particles detached from the vessel wall during the treatment. The first occlusion catheter 4 and treatment catheters 15, 22, 15' are inserted and retracted through an insertion catheter 12 having a third tubular shaft 13 with a through lumen 14.

**[0012]** According to FIG. 1 the plaque deposit 3 is forced into the wall of the vessel portion 1 by known balloon dilatation technique performed with a dilatation catheter 15 having a second tubular shaft 16 with a central lumen 17 (not shown) extending therethrough for coaxial reception of the first occlusion catheter 4 and being longitudinally displaceable with respect to the first occlusion catheter 4. After dilation the dilatation balloon 18 is emptied and withdrawn through the insertion catheter 12 over the first occlusion catheter 4.

**[0013]** FIG. 2 shows the proximal end 6 of the first occlusion catheter 4 which is connected to a stop cock 19. Before balloon dilatation the distal occlusion balloon 8 was filled with an inflation medium such as physiological saline or fluoroscopic contrast which is set under pressure for example by a syringe (not shown) placed into the proximal opening 20 of the stop cock 19. The pressurized condition is maintained during the treatment procedure by switching the stop cock 19 into its locking position. After balloon dilatation the dilatation catheter 15 can only be withdrawn until it reaches the stop cock 19 as it was in the prior art situation.

**[0014]** In oder to remove the dilatation catheter 15 completely from the first occlusion catheter 4 the inflation lumen 9 is occluded by clamping or kinking the first tubular shaft 5 distal of the stop cock 19. In this state the stop cock 19 is replaced by a seal 21 which is plugged into the proximal entry 10 of the inflation lumen 9. According to FIG. 3 the seal 21 has an outside dimension small enough to fit within the central lumen 17 of the dilatation catheter 15 which therefor can be withdrawn proximally from the sealed first occlusion catheter 4. The occlusion catheter 4 still fulfills its function of occluding the vessel 1 downstream of the treatment portion and is ready to receive another treatment catheter if indicated.

**[0015]** In case the widened stenosis requires stenting, i.e. scaffolding the treated vessel portion 1 by implanting a vessel supporting tubular member to prevent resteno-

sis, a stent delivery instrument 22, as shown in FIG. 4, loaded with a self-expanding stent 23 is introduced over the first occlusion catheter 4. For insertion the self-expanding stent 23 is radially compressed and kept in a small diameter state between an inner shaft 24 and an outer shaft 25 which are axially shiftable relative to each other. The stent 23 is released by retraction of the outer shaft 25 so that the stent 23 can expand and conformingly support the inner wall of vessel portion 1. After the self-expanding stent 23 is fully set free the stent delivery instrument 22 is withdrawn through the insertion catheter 12 and can be removed completely from the first occlusion catheter 4.

**[0016]** According to FIG. 5, again a dilatation catheter 15' is introduced which may have different diametral and/or longitudinal sizes in its dilatation balloon 18'. It is used to perform a post-dilation if the treated stenosis has not yet reached the required patency and it further anchors the implanted stent 23 within the wall of the vessel portion 1.

**[0017]** In FIG. 6 the dilatation catheter 15' is retracted and the stent 23 is engaged with the vessel portion 1 as desired. Before emptying the distal occlusion balloon 8 any particles which may have been detached from the vessel wall during the treatment are removed by suction via the through lumen 14 of the insertion catheter 12 as it is known from the state of the art.

## List of Reference Signs

**[0018]**

| | |
|---|---|
| 1 | vessel portion |
| 2 | side branch |
| 3 | plaque deposit |
| 4 | first occlusion catheter |
| 5 | first tubular shaft |
| 6 | proximal end |
| 7 | distal end |
| 8 | distal occlusion balloon |
| 9 | inflation lumen |
| 10 | proximal entry |
| 11 | distal exit |
| 12 | insertion catheter |
| 13 | third tubular shaft |
| 14 | through lumen |
| 15 | dilatation catheter (treatment catheter for pre-dilatation) |
| 15' | dilatation catheter (treatment catheter for post-dilatation) |
| 16 | second tubular shaft |
| 17 | central lumen |
| 18 | dilatation balloon (for pre-dilatation) |
| 18' | dilatation balloon (for post-dilatation) |
| 19 | stop-cock |
| 20 | proximal opening |
| 21 | seal |
| 22 | stent delivery instrument (treatment catheter) |
| 23 | self-expanding stent |
| 24 | inner shaft |
| 25 | outer shaft |

## Claims

1. Catheter device for the treatment of a vessel carrying body fluid, comprising an inner first occlusion catheter (4), having a first tubular shaft (5) with a proximal end (6) and a distal end (7), a distal occlusion balloon (8) disposed at the distal end (7) of the first tubular shaft (5) and an inflation lumen (9) extending through the first tubular shaft (5) between a proximal entry (10) at the proximal end (6) and a distal exit (11) inside the distal occlusion balloon (8), and an outer treatment catheter (15, 22, 15'), having a second tubular shaft (16) with a central lumen (17) extending therethrough for coaxial reception of the first occlusion catheter (4), and being longitudinally displaceable with respect to the first occlusion catheter (4),
characterized by a seal (21) for the proximal entry (10) of the inflation lumen (9), having an outside dimension small enough to fit within the central lumen (17) for advancing, resp. withdrawing, a treatment catheter (15, 22, 15') proximally onto, resp. from, the sealed first occlusion catheter (4).

2. Catheter device according to claim 1,
characterized by the treatment catheter being a dilatation catheter (15, 15') further having a non-compliant dilatation balloon (18, 18').

3. Catheter device according to claim 2,
characterized by the dilatation catheter (15) further having a balloon-expandable stent mounted on the dilatation balloon (18).

4. Catheter device according to claim 1,
characterized by the treatment catheter being a stent delivery instrument (22) loaded with a self-expanding stent (23).

5. Catheter device according to claim 1,
characterized by the treatment catheter being a second occlusion catheter further having a proximal occlusion balloon for sealing a vessel portion (1) between the proximal and distal occlusion balloon (8).

6. Catheter device according to claim 5,
characterized by an annular lumen disposed between the first and second occlusion catheter (4) and extending between a proximal inlet and a distal outlet for the infusion, resp. aspiration, of a liquid into, resp. from, the sealed vessel portion (1).

7. Catheter device according to anyone of the preced-

ing claims,
characterized by further comprising an outer insertion catheter (12) having a third tubular shaft (13) with a through lumen (14) for insertion, resp. retraction, of the first occlusion catheter (4) and of a treatment catheter (15, 22, 15') into, resp. from, the vessel.

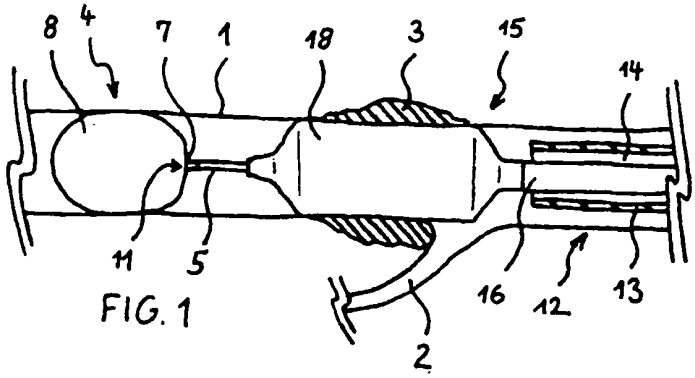


FIG. 1

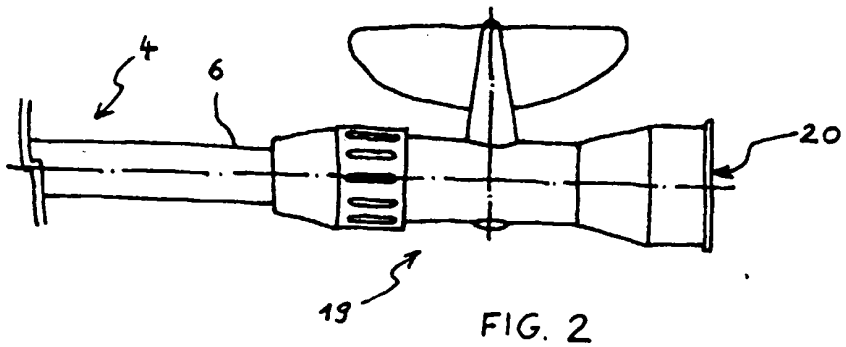


FIG. 2

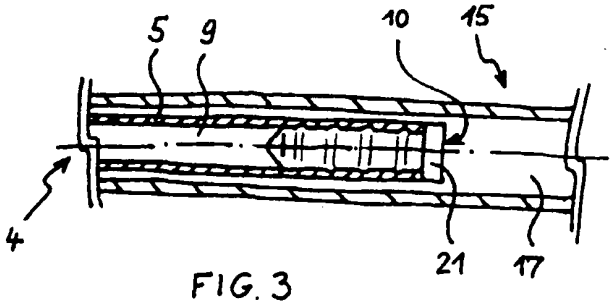


FIG. 3

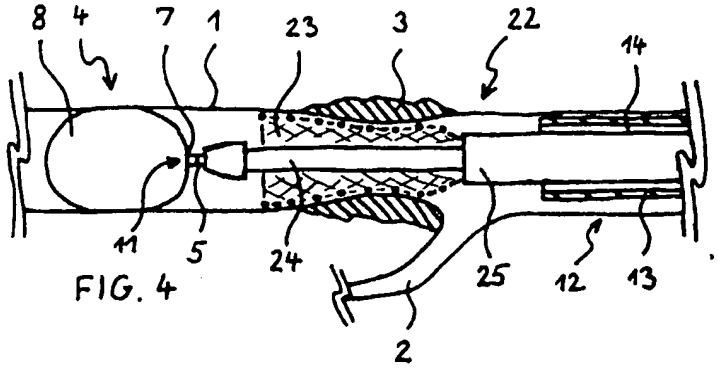


FIG. 4

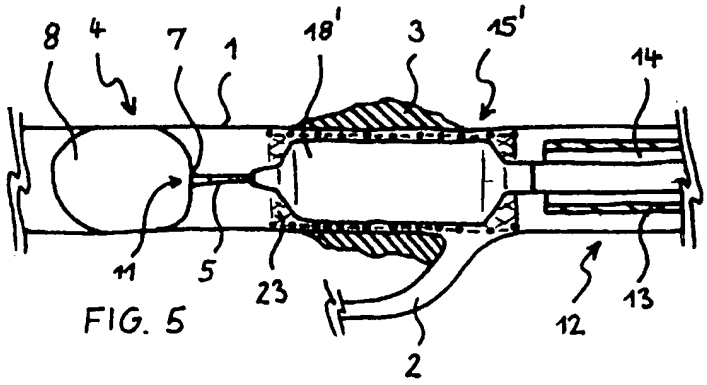


FIG. 5

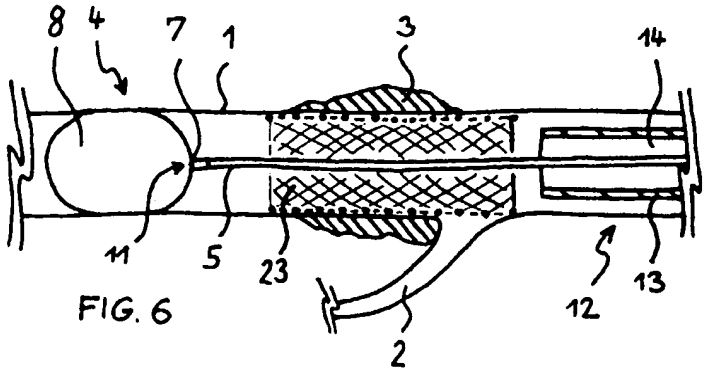


FIG. 6

European Patent Office

# EUROPEAN SEARCH REPORT

Application Number
EP 97 20 3280

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (Int.Cl.6) |
|---|---|---|---|
| A | EP 0 277 367 A (ADVANCED CARDIOVASCULAR SYSTEM) * abstract * * column 2, line 21 - line 50 * * column 3, line 13 - line 24 * * column 9, line 46 - column 10, line 8; figures 1,4,9 * | 1,2,5-7 | A61M29/02 |
| A | US 5 158 553 A (BERRY ET AL.) * abstract * * column 1, line 39 - line 47 * * column 2, line 7 - line 16; figures 1-6 * | 1,6 | |
| A | EP 0 747 088 A (PARODI ) * abstract * * column 6, line 37 - line 48 * * column 7, line 58 - column 8, line 8; figures 2,3,7-10 * | 1-7 | |
| A | US 5 462 529 A (SIMPSON ET AL.) * abstract * * column 2, line 35 - line 67; figures 1,7-9 * | 1,2,5-7 | TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61M A61F |
| A | US 5 397 307 A (GOODIN ) | | |

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| THE HAGUE | 17 March 1998 | Michels, N |

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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& : member of the same patent family, corresponding document

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